UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	HON. ROBERT B. KUGLER Civil No. 19-2875 (RBK/JS)

THE TEVA DEFENDANTS' MOTION TO QUASH PLAINTIFFS' THIRD-PARTY SUBPOENAS AND FOR PROTECTIVE ORDER TO ENJOIN OR LIMIT COLLECTION OF IRRELEVANT INFORMATION BY THIRD-PARTY SUBPOENA

Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries Ltd., Actavis LLC, Actavis Pharma, Inc., and Arrow Pharm (Malta) Ltd. (hereinafter "Teva" or "the Teva Defendants"), pursuant to Federal Rule of Civil Procedure 45(d)(3), hereby file this Motion to Quash the Plaintiffs' Subpoenas issued to aaiPharma Inc., Cobalt Pharmaceuticals Inc., MSN Laboratories Private Ltd., Ratiopharm, Zhejiang Menovo Pharmaceutical Co., Ltd., Catalent Inc., Chemir Pharma Services, Envoy Health Care LLC, Gibralter Laboratories, Inc., Integrated Analytical Laboratories, LLC, International Trading Pharmaceuticals Laboratories, Inc., Jost Chemical Co., Jubilant Generics, Prevalere Life Sciences Inc., SGS US Testing Co. Inc., Southern Testing & Research Laboratories, Spectral Data Services Inc., and WRB Corp. (hereinafter "Third Parties") and aver as follows:

I. Facts and Procedural Background

1. The Third Parties consist of entities including vendors, manufacturers, re-labelers, repackagers, and testing consultants, and are all[1] non-parties to this litigation.

2. On or about October 16, 2020, Plaintiffs' counsel provided Defendants' counsel for numerous API and finished dose manufacturing parties (hereafter, "Defendants") with copies of broad and open-ended subpoenas that were "in the process of being served on" the Third Parties, seeking documents, communications and information related: (1) the identification of employees,

[1] The Teva Defendants note that at least one entity, Jubilant Generics, appears to be a related entity to Jubilant Cadista Pharmaceuticals Inc., which is a named Defendant though no attorney has entered an appearance on behalf of this entity.

agents, or third parties responsible for or involved in twelve separate categories of activity, including Sartan recalls, Sartan withdrawals, Sartan audits, Sartan validation, and regulatory compliance; (2) contracts with "any Defendant" related "in any way" to various topics, including ARB drugs, cGMP compliance, FDA advocacy or communications, public relations relating to the ARB drug recalls, or recall management; (3) communications with Defendants regarding the FDA's investigation into nitrosamine contamination, as well as a privilege log regarding the same; (4) ANDA and DMF file documents regarding the filing or supplementation of any Drug Master File relating to any ARB drug; (5) nitrosamines, nitrosamine contamination, nitrosamine investigations, toxicology assessments, CAPAs, risk assessments, and other topics; (6) recall-related documents, including recalls, recall decisions, destruction or disposal of ARB drugs or API, recall letters, and return authorizations; (7) storage, quarantine, destruction, preservation, or testing of recalled or withdrawn ARB products or API; (8) communications with the FDA; (9) testing data related to nitrosamine contamination or nitrosamine impurities; (10) solvent manufacturing, recovery, and recycling; and (11) toxicology assessments. *See Subpoenas served on Third Parties, attached as Exhibit "A."*

3. The eleven aforementioned categories of requests encompass numerous requests by Plaintiffs for "communications" and "documents" pertaining to the requests. *See Exhibit "A."*

4. Plaintiffs' definitions of "communications" and "documents" are all-encompassing, and do not make any provision or exception for "communications" or "documents" subject to the attorney-client privilege, the work product doctrine, or this Honorable Court's Confidentiality and Protective Order as outlined in Dkt. 139. *See Id.*

5. Plaintiffs' subpoenas further include sweeping requests for documents and communications beyond the scope of this Honorable Court's rulings on macro discovery issues (*see* corrected Order entered November 26, 2019), as the subpoenas request information related to all products and are not limited to Valsartan products. *See id., Schedule A (definitions of "sartan," "ARB," "recalled products," and "Active Pharmaceutical Ingredient").*

6. Plaintiffs' counsel did not comply with the requirements of Federal Rule of Civil Procedure 45 insofar as Plaintiffs have failed to give notice to Defendants of the effective service date of any of the subpoenas to any of the Third Parties, beyond stating that the subpoenas were "in the process" of being served.

7. Defendants' counsel has requested clarification of the service date(s) of the subpoenas upon the Third Parties, and Plaintiffs' counsel has not responded.

8. The Teva Defendants lack full knowledge and notice of what specific information or documentation each Third Party possesses. Nevertheless, as the Teva Defendants have or had a variety of confidential business and professional relationships with the Third Parties, many of which extend well beyond the subject matter of this litigation and the scope of this Court's rulings on macro discovery issues, as well as information or documents protected by this Honorable Court's Confidentiality and Protective Order, the attorney-client privilege, and the work product doctrine, the Teva Defendants have a direct interest in protecting their confidential and privileged documents and information in the possession, custody, or control of the Third Parties. The Teva Defendants also have a continuing interest in ensuring discovery in this case is relevant and proportional to the needs of the case.

II. Standing

9. Any party to this action "will have standing to quash or modify a non-party subpoena when it claims a privilege or privacy interest in the information sought from the nonparty." *Schmulovich v. 1161 Rt. 9 LLC*, No. CIV.A. 07-597FLW, 2007 WL 2362598, at *2 (D.N.J. Aug. 15, 2007) (citing *Thomas v. Marina Assocs.*, 202 F.R.D. 433, 434–435 (E.D. Pa. 2001)). *See also Malibu Media, LLC v. John Does 1-18*, Civ. A. No. 12-07789 (KM) (MCA), 2014 WL 229295, at *6 (D.N.J. Jan. 21, 2014); *Patrick Collins, Inc. v. John Does 1-13*, Civ. A. No. 12-7620 (PGS), 2013 WL 3466833 at *2 (D.N.J. July 10, 2013); *Schmulovich*, 2007 WL 2362598, at *2.

10. In addition to having standing to quash a subpoena seeking privileged or private information or documents, a party also has standing under Fed. R. Civ. P. 26(c) to move for a protective order enjoining or limiting "subpoenas issued to non-parties which seek irrelevant information." *US EEOC v. United Galaxy*, Civil Action No. 10-4987 (ES-CLW), 2011 U.S. Dist. LEXIS 103398, at *5-6 (D.N.J. Sep. 13, 2011) (quoting *In re Remec, Inc. Sec. Litig.*, Civil No. 04cv1948 JLS (AJB), 2008 U.S. Dist. LEXIS 47412, at *4 (S.D. Cal. May 30, 2008)).

11. In this case, Plaintiffs' subpoenas directed to the Third Parties seek information protected by the attorney-client privilege and the work product doctrine, seek confidential and proprietary business information, and encompass irrelevant information beyond the scope of this Honorable Court's rulings on macro discovery issues.

III. Legal Argument

12. Fed. R. Civ. P. 45 directs this Court to quash a subpoena that "requires disclosure of privileged or other protected matter, if no exception or waiver applies[.]" Fed. R. Civ. P. 45(d)(3)(A)(iii). Additionally, discovery sought via a subpoena issued pursuant to Rule 45 must fall within the scope of discovery permissible under Rule 26(b). *OMS Investments, Inc. v. Lebanon Seaboard Corp*., Civil Action No. 08-2681 (AET), 2008 U.S. Dist. LEXIS 94165, *2 (D.N.J. Nov. 18, 2008).

13. Fed. R. Civ. P. 26(b)(1) defines the outer boundaries of permissible discovery to which subpoenas must conform:

> **Unless otherwise limited by court order**, the scope of discovery is as follows: Parties may obtain discovery regarding any **nonprivileged matter** that is relevant to any party's claim or defense and **proportional to the needs of the case**, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit. Information within this scope of discovery need not be admissible in evidence to be discoverable.

15. Plaintiff's subpoenas to the Third Parties facially seek documents and information this Court has already determined to be privileged and protected, as well as documents and information that are neither relevant nor proportional to the needs of the case. These requests invade the Teva Defendants' direct interests in maintaining the confidentiality of their privileged, proprietary, and private documents, and in preventing this litigation from devolving into incessant demands for matters beyond the subject matter of the parties' dispute.

A. Plaintiffs' Subpoenas Seek Privileged and Confidential Documents and Information

16. This Court has already entered a Confidentiality and Protective Order (Dkt. 139) contemplating that the documents and information described by plaintiffs' subpoenas to the Third Parties constitute protected documents and information, including confidential and proprietary documents and business information. *See Confidentiality and Protective Order*, Dkt. 139 at ¶ 14. Plaintiff's subpoenas also call for documents and information that, by description, encompass materials facially protected by attorney-client privilege or the work product doctrine, and use overbroad, vague, and ambiguous terminology potentially encompassing additional communications and documents protected by attorney-client privilege, the work product doctrine, and the Confidentiality and Protective Order.

17. Because the Teva Defendants do not have access to or knowledge of the details of the Third Parties' files, they cannot supply a log of the specific privileged, private, and confidential documents in the Third Parties' possession, custody, or control that implicate the Teva Defendants' privilege and confidentiality interests. But Plaintiffs' requests facially encompass documents and information that, due to the confidential business and professional relationships between the Teva Defendants and the Third Parties, are or may be subject to claims of privilege or confidentiality designations by the Teva Defendants. The categories of potentially privileged or confidential documents sought by the subpoenas include:

- Contracts between the Third Parties and Teva and other contract-related documents pertaining to ARB drugs, "cGMP compliance," "FDA advocacy or communication," "public relations," "crisis management" and "recall management," *see Exhibit "A", Schedule A, "Contracts" Requests 1-3*;
- Communications between the Third Parties and Teva and other documents relating to the FDA's investigation into the nitrosamine contamination, including any inspection of a facility where any ARB drug is manufactured, *see id., "Communications with Relevant Parties" Requests 1-2*;
- Communications between the Third Parties and Teva and other documents relating to the filing or supplementation of any Drug Master File relating to any ARB drug, *see id., "ANDA and DMF File Documents" Request 1*;
- Communications between the Third Parties and Teva and related documents relating to nitrosamines, nitrosamine contamination, nitrosamine investigation, and related topics, *see id., "Nitrosamine Communication" Requests 1-10*;
- Communications between the Third Parties and Teva and other documents related to recalls, recall decisions, destruction or disposal of ARB drugs or API, recall letters, and return authorizations, *see id. "Recall-Related Documents" Requests 1-4*;

- Communications between the Third Parties and Teva and other documents relating to storage, quarantine, destruction, preservation, or testing of recalled or withdrawn ARB products or API, *see id. "Quarantine and/or Destruction" Requests 1-5*;
- Communications between the Third Parties and Teva and other documents relating to communications with the FDA, *see id. "Communications with the FDA" Requests 1-6*;
- Communications between the Third Parties and Teva and other documents relating to testing data related to nitrosamine contamination or nitrosamine impurities, *see id. "Testing Data" Requests 1-4*;
- Communications between the Third Parties and Teva and other documents relating to solvent manufacturing, recovery, and recycling, *see id. "Solvent Manufacturing, Recovery, and Recycling" Requests 1-6*; and
- Communications between the Third Parties and Teva and other documents relating to toxicology assessments, *see id. "Toxicology Assessments" Requests 1-4*.

18. Plaintiffs' subpoenas demonstrate that Plaintiffs know how to exclude privileged documents from the scope of their requests and to seek a privilege log (*see, e.g., "Communications with Relevant Parties" Requests 1-2*), yet Plaintiffs provided for such an exclusion of privileged documents in only one category of their document requests (*see id*.), and made no provision for the exclusion of confidential or proprietary documents and information from any their requests. That leaves the Teva Defendants in the untenable position of facing subpoenas to the Third-Parties that facially demand production of the Teva Defendants' privileged and confidential documents and information, yet make no provision for the identification and exclusion of such privileged and confidential documents.

18. Because Plaintiffs have failed to tailor the requests in the subpoenas to exclude privileged and confidential documents in which the Teva Defendants have a direct interest, and Plaintiffs' subpoenas facially request categories of documents likely to encompass such privileged and confidential documents, the Court should quash the subpoenas and direct Plaintiffs to issue new subpoenas that exclude privileged and confidential documents across all categories of requests. Alternatively, the Court should issue a protective order granting the Teva Defendants an opportunity to review the Third Parties' anticipated productions, to withhold privileged documents from the productions subject to this Court's resolution of any challenged privilege designations, and to designate documents for protection pursuant to the Court's Confidentiality and Protective Order.

B. Plaintiffs' Subpoenas are outside the Scope of Discovery as Provided by the Federal Rules and as Limited by this Honorable Court

19. Plaintiffs' requests not only encompass privileged and confidential documents and information, but also materials patently irrelevant to the subject matter of this litigation and disproportionate to the needs of the case. This Court issued an Order on macro discovery wherein plaintiffs' requests for information pertaining to products other than Valsartan were denied. *See Corrected Order dated November 26, 2019* at ¶ 4. In disregard of that Order, the subpoenas to the Third Parties transgress the limits this Court has put in place and seek unbounded discovery on all manner of subjects outside the claims and allegations before this Court. Plaintiffs cannot use third-party discovery as a vehicle to extract from non-parties the very types of documents and information this Court has prohibited in the context of party discovery. Defendants are entitled to a protective order enjoining and limiting Plaintiffs' excessive discovery requests to ensure that the Teva Defendants are not forced to participate in discovery on collateral issues from the Third Parties that this Court has barred Plaintiffs from taking from Defendants directly. *See United Galaxy*, 2011 U.S. Dist. LEXIS 103398, at *5-6.

20. Each of Plaintiffs' eleven categories of requests seeks irrelevant documents and information and is disproportionate to the needs of the case, and should therefore be enjoined or limited by protective order.

21. Plaintiffs' first category of requests, documentation pertaining to the Third Parties' Corporate Organization, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all Sartan drugs and is not limited to the recall of Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

22. Plaintiffs' second category of requests, documentation pertaining to Contracts, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

23. Plaintiffs' third category of requests, communications with relevant parties, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

24. Plaintiffs' fourth category of requests, ANDA and DMF File Documents, is overbroad, unduly burdensome, and not proportionate to the needs of the Action in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

25. Plaintiffs' fifth category of requests, "communications" and "documents" related to nitrosamine contamination, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

26. Plaintiffs' sixth category of requests, related to recall related documents, seeks "documents" and "communications" regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

27. Plaintiffs' seventh category of requests, related to quarantine and/or destruction, seeks "communications" and "documents" regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

28. Plaintiffs' eighth category of requests, related to communications with the FDA, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

29. Plaintiffs' ninth category of requests, related to testing data, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

30. Plaintiffs' tenth category of requests, related to solvent manufacturing, recovery, and recycling, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

31. Plaintiffs' eleventh category of requests, related to toxicology assessments, is overbroad, unduly burdensome, and not proportionate to the needs of the Actions in that it seeks documents regarding all ARB drugs and is not limited to Valsartan and, therefore, goes beyond the scope of the Court's rulings on the macro discovery issues.

C. Plaintiffs Failed to Comply with the Requirements of Federal Rule of Civil Procedure 45

35. Fed. R. Civ. P. 45 provides:

> [i]f the subpoena commands the production of documents, electronically stored information, or tangible things or the inspection of premises before trial, then before it is served on the person to whom it is directed, a notice and a copy of the subpoena must be served on each party.
>
> FRCP 45(a)(1).

36. This notice requirement contemplates that the Plaintiffs would be required to give notice to Defendants prior to serving the subpoenas on the Third Parties. *See Coleman-Hill v. Governor Mifflin Sch. Dist.*, 271 F.R.D. 549, 552 (E.D. Pa. 2010) (citations omitted).

37. As Plaintiffs failed to provide notice to Defendants prior to serving the subpoenas, and to this day have not confirmed which Third Parties have been served or when, Plaintiffs have failed to comply with the requirements of Rule 45.

IV. Conclusion

38. Based on the forgoing, Plaintiffs' subpoenas on the Third Parties invade the Teva Defendant' privileged and confidential documents and exceed the limits this Court has placed on discovery through its rulings on macro discovery issues.

39. Accordingly, Plaintiffs' subpoenas issued to the Third Parties should be quashed, and this Court should further issue a protective order enjoining or limiting the scope of the subpoenas, together with such other and further relief as the Court deems necessary or appropriate.

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Respectfully submitted,

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